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Report of the Secretary-General

Addendum

Environmentally sound management of biotechnology*

(Chapter 16 of Agenda 21)

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INTRODUCTION

1. The present report reviews progress made in the implementation of the objectives set out in chapter 16 (Environmentally sound management of biotechnology) of Agenda 21,[1] taking into account the decision taken by the Commission on Sustainable Development on that subject at its third session in 1995. Those objectives are set out relative to the following five programme areas: (a) increasing the availability of food, feed and renewable raw materials; (b) improving human health; (c) enhancing protection of the environment; (d) enhancing safety and developing international mechanisms for cooperation; and (e) establishing enabling mechanisms for the development and environmentally sound application of biotechnology.

2. Biotechnology can contribute to sustainable development by improving food production and feed supply, health care and environmental protection. Information provided by national Governments to the Commission shows that many developed and developing countries are undertaking efforts in biotechnology research and development and are establishing policies related to the sustainable use and management of biotechnologies. The number of private-sector companies involved in biotechnology research and development or showing a vital interest in its results is growing.

Box 1. Interests of countries in biotechnology use is growing

In 1995, the Health and Safety Executive of the United Kingdom of Great Britain and Northern Ireland had notification of 470 centres that are carrying out activities involving the contained use of genetically modified organisms. There are also many large and multinational companies with substantial interests in biotechnology, and in addition about 150 small and medium-sized enterprises whose operations are based on biotechnology research and development.

Between 1984 and 1993, the National Centre for Genetic Engineering and Biotechnology of Thailand allocated US$ 9 million to university research and development in biotechnology, inter alia, to support the use of biopesticides and reduce the use of chemical fertilizers by promoting the use of biofertilizers.

3. Several United Nations bodies and other international organizations have strengthened their biotechnology and related support programmes or developed new initiatives to assist efforts being undertaken by developing countries and economies in transition. Through cooperation programmes, the access of those countries to biotechnology information and applications has improved, and the adaptation of biotechnological solutions to the conditions of particular clients has been facilitated.

4. The increasing recognition that biotechnology can provide solutions for many problems fundamental to sustainable development makes it essential to

establish national legislation to ensure the adequate protection of human health and the environment in connection with the contained use and release of genetically modified organisms resulting from modern biotechnologies. Moreover, it calls for internationally agreed guidelines or principles of risk assessment and risk management to be applied in the development, transboundary movement and use of biotechnology solutions.

I. PROGRESS ACHIEVED IN THE IMPLEMENTATION OF THE OBJECTIVES OF THE SELECTED TWO PROGRAMME AREAS

5. Consistent with the conclusions of inter-sessional meetings on issues related to the environmentally sound management of biotechnology, and the decisions on biotechnology adopted by the Commission at its third session, in 1995, progress in two programme areas is reported on below.

A. Establishing enabling mechanisms for the development and environmentally sound application of biotechnology

6. Important for the sustainable use of biotechnologies is the establishment of an effective and transparent national decision-making structure to deal with the legal and policy issues related to the safe and sound management of biotechnologies. An increasing number of countries have developed or are in the process of developing regulatory oversight systems for biotechnology applications that contain guidelines or principles on biotechnology risk assessment and risk management. In order to take account of public concerns relative to safeguarding environmental health and safety in the use of modern biotechnologies, efforts are being made to ensure active participation by the public at large in the discussion on and implementation of those policies.

Box 2. Establishing biosafety mechanisms at the national level

The purpose of the Finnish Gene Technology Act is to promote the safe and ethically acceptable use of gene technology. The legislation contains principles on biotechnology risk assessment and management. Consultations with public and private-sector groups and with communities is a key feature.

In Brazil, specific legislation was sanctioned in 1995 and a number of biosafety regulations were adopted related to biosafety in laboratories and the release of genetically modified organisms into the environment. In order to enhance awareness and transparency several TV programmes are devoted to the potential benefits and risks arising from the application of biotechnology, taking into account ethical and cultural considerations.

Malaysia's biosafety guidelines to control the release of genetically modified organisms and biotechnology products are in the final stage of preparation. Mass media, including newspapers, TV and radio, are actively involved in awareness-raising and education of the public on biosafety issues.

7. The ways and extent to which government policy is used to support or promote biotechnology vary considerably among countries. In developed countries, policy instruments are mainly aimed at strengthening the competitive positions of those countries in the area of biotechnology, and involve science and technology, industrial, trade and economic policy, and government interaction with the private sector. In view of international competition Governments are increasingly becoming willing to intervene in the market. In the majority of developing countries, the question of national policy for biotechnology is singularly important. In many instances, policy initiatives are already being undertaken with varying degrees of success.

8. A major policy challenge concerns the ability to be selective in the promotion of biotechnology so as to optimize social and economic returns on scarce resources in ways that are compatible with overall economic policies and development strategies. Policy makers in developing countries are faced with the dilemma of choosing between long-term solutions through technology transfer and capacity-building, including through cooperative arrangements with developed countries, and short-term solutions utilizing conventional methods and improvements of their information and management practices.

9. Essential for success in developing capabilities in the safe and sound use and management of biotechnologies appear to be the establishment of relevant research and development programmes, fostering research potential through a steady supply of qualified personnel, making investment capital available and providing private-sector incentives to invest in biotechnology.

Box 3. Capacity-building in biotechnology

The University of Havana, Cuba, offers postgraduate studies in biosafety, and a number of universities in Bolivia implement training programmes in biotechnology. Malaysia is making available research and development results in biotechnology produced in public institutions to the private sector at no cost in order to strengthen the linkages between research and development activities and the commercialization of biotechnologies, and to encourage collaboration between the public and private sectors.

10. Lack of human and material resources can to some extent be compensated through building up research networks as a means of increasing critical mass. Extensive use of communication and multimedia technologies can enhance the effectiveness of such networks, and in addition can provide a cost-effective means of upgrading scientific and technological skills.

11. Facilitator mechanisms effecting the transfer of proprietary technologies to public and private institutions in the developing world are also likely to have significant impacts on upgrading scientific and technological capacity.

12. Intellectual property rights and biosafety play a key role in building long-term competitive advantage. National policies to protect proprietary rights in intellectual property are important to stimulate research and

development in biotechnology, attract private-sector investment and promote biotechnology transfer, while ensuring that public health and environmental safety are not compromised.

13. At the international level, aid programmes have reduced their commitment to the development of long-term training and research efforts in the agricultural and medical sectors. Hence, the success of international programmes depends on ensuring that the cycle of market research, priority setting, strategic and applied research, technology transfer and feedback remains operative.

B. Enhancing safety and developing international mechanisms for cooperation

14. The need for further efforts leading to international agreement on principles to be applied in risk assessment and the management of all aspects of biotechnology is widely recognized. The report of the European Community to the Commission on Sustainable Development at its third session, for example, stated that only when adequate and transparent safety and border-control procedures are in place will the Community at large be able to derive maximum benefit from and be in a better position to accept the benefits and risks of biotechnology. A considerable number of non-governmental organizations, women groups and indigenous people in both developed and developing countries have expressed concern that the promotion of biotechnology is quite undesirable without some international mechanism in place to protect people from possible adverse effects resulting from genetically altered foods and animals, as well as from disadvantages that a biotechnology-driven market might bring to small farmers in developing countries.

15. Disparities in the definition of regulated items and the scope of regulations and assessment procedures in different countries may potentially compromise public health and environmental safety. In some cases, it may also lead to unfair trade practices. International cooperation is therefore essential in minimizing regulatory contradictions among individual national systems and ensuring the harmonization of risk-assessment procedures to the extent possible. Such cooperative efforts are already under way. The United Nations Industrial Development Organization (UNIDO), for example, has established the Biosafety Information Network and Advisory Service. Its cooperation with the Expert Group for Harmonization of Regulatory Oversight in Biotechnology of the Organisation for Economic Cooperation and Development has resulted in the establishment of an integrated database on biotechnology regulations and risk-assessment procedures.

16. In parallel, the Conference of the Parties to the Convention on Biological Diversity, at its second meeting in Jakarta in November 1995, decided to establish an open-ended ad hoc working group of government-designated experts to develop a protocol on biosafety in the field of the safe transfer, handling and use of living modified organisms. The protocol is to have a specific focus on the transboundary movement of any living modified organism resulting from modern biotechnology that might lead to adverse effects on the conservation and sustainable use of biological diversity, and is to set out for consideration an appropriate procedure for advance informed agreement. During the Jakarta

meeting, it was also agreed that the UNEP guidelines may be used as an interim mechanism during the development of the protocol and to complement it after its conclusion. An open-ended ad hoc working group of experts established under the Convention on Biological Diversity met for the first time at Aarhus, Denmark, from 22 to 26 July 1996, to discuss the elements and structure of the protocol.

Box 4. Initiative of the United Nations Environment Programme (UNEP) on international biosafety guidelines

A UNEP-led initiative resulted in the adoption of the International Technical Guidelines for Safety in Biotechnology by a global consultation of government-designated experts held at Cairo in 1995. The Guidelines were formulated on the basis of common elements and principles derived from relevant national, regional and international instruments, regulations and guidelines, and drew upon experience already gained through their preparation and implementation. An international workshop to follow up on the Guidelines, which was held in Buenos Aires from 31 October to 1 November 1996, adopted recommendations on capacity-building related to biosafety.

17. Finally, another notable development has been the Fourth International Technical Conference for Plant Genetic Resources, which was held at Leipzig from 17 to 23 June 1996. The Conference was convened by the Food and Agriculture Organization of the United Nations (FAO) with the intention of translating the relevant parts of Agenda 21 and the Convention on Biological Diversity into a global plan of action. The Conference resulted in a plan of action that includes some 346 recommendations derived from a background report entitled "State of the world's plant genetic resources". It also resulted in a declaration on conservation and sustainable utilization of plant genetic resources for food and agriculture. The declaration formulates general rules and principles on access to and conservation and use of plant genetic resources.

II. TRENDS RELEVANT FOR THE FURTHER IMPLEMENTATION OF THE OBJECTIVES SET OUT IN CHAPTER 16 OF AGENDA 21

18. A growing number of developing countries and economies in transition have realized the considerable scope that exists for achieving productivity gains, improvement in the quality of food and agricultural products, and conservation of the environment by using modern biotechnologies as an adjunct to existing technologies and methods. Progress is becoming noticeable particularly where efforts have been geared to channel an important part of biotechnology capacity-building towards the effective exploitation of existing knowledge. That in no way diminishes the need for developing countries to build domestic skills and capabilities in the biosciences; on the contrary, it is in countries that have the strongest science and technology base that the use, assimilation and adaptation of existing knowledge becomes part of the cumulative learning process leading to upgrading their research and development capability.

19. A number of countries have achieved significant progress through the successful implementation of industrial and technology policies. For example, the Asian newly industrialized countries have been particularly skilful in deploying industrial policy to promote commercial biotechnology. They use grants, direct capital investment and fiscal stimulants, and support skill-building and downstream development. Some countries have made systematic use of foreign technology licensing and the repatriation of scientists trained abroad to strengthen their relatively weak research bases. In Latin America, most Governments have tended to confine their activities to research and development support. Although some of the larger countries are beginning to develop more comprehensive approaches to bio-policy, it will be some time before that shift begins to have an impact on society and the economy.

20. Genome research in key species has generated a large amount of information and spin-off technologies in the public domain that are increasingly being utilized in target-oriented research relevant to developing countries. In parallel, the proliferation of electronic information accessible on the Internet is beginning to have major beneficial impacts on research and education.

21. At the international level, in vitro micropropagation and recombinant DNA technologies for the conservation and exchange of genetic diversity of crops important to the developing world have already been transferred to national programmes, mainly through Consultative Group on International Agricultural Research centres. Similarly, genetic engineering has been successfully deployed in research programmes for diagnostics, drug and vaccine development of the World Health Organization; the International Green Cross; the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases; and the International Centre for Genetic Engineering and Biotechnology.

III. CONSTRAINTS AND UNFULFILLED EXPECTATIONS

22. To date, in many developing countries, the actual contribution that biotechnology can make to solve fundamental problems of development and environment remain below the expectations foreseen by the United Nations Conference on Environment and Development. As for the ground-level social benefits of biotechnology, they have yet to make themselves widely felt; that is not surprising, however, in view of the fact that health care and agricultural biotechnology are only now appearing in the market place, even in the industrialized world.

23. A considerable number of developing countries still lack the level of biotechnology capacity required to undertake research and development in biotechnology or to fully benefit from biotechnological solutions available in the market. The obstacles to building up biotechnology capability and capturing its social and private returns still remain in most developing countries. Early expectations that biotechnology would make a significant contribution to achieving sustainable development while safeguarding the environment are being fulfilled only slowly. Constraints include: (a) scarcity of human and financial resources; (b) low institutional capacity; (c) lack of coherent realistic policies in some countries, and on occasions lack of political will; and (d) inadequate awareness and understanding of the potential benefits and

risks of the technology, as well as of the requirements for its environmentally sound management.

24. The observable reduction of international funding for research and programmes addressing problems of the developing world is a trend affecting many sectors. Indeed, available information indicates levels of financial support far below those that are minimally required to enable developing countries to participate in and benefit from the use of biotechnology.

25. There is growing concern among several developing countries about the increasing interest of foreign private companies in using the knowledge of indigenous people for private gain. They argue that the Trade-Related Intellectual Property Rights provisions of the World Trade Organization work to the advantage of private companies and laboratories, who are able to commercialize such products as medicine or seeds based on the knowledge of indigenous people or communities. On the other hand, intellectual property rights systems deny protection to the knowledge and innovations of indigenous people or communities because it is deemed to be in the public domain and therefore to be freely available. Accordingly, the need to safeguard private investment through strong intellectual property regimes must be compensated by workable arrangements that ensure equitable sharing of socio-economic benefits with the developing world.

26. The negotiations under the Convention on Biological Diversity on internationally agreed guidelines or principles of risk assessment and risk management to be applied in the development, transboundary movement and use of biotechnological solutions has been slow because of the differences in national interests. Some countries are in favour of limiting the scope of the proposed protocol mainly to the transboundary movement of living modified organisms. They argue that such a protocol should aim at greater harmonization of existing regulations and accept the concept of substantial equivalence. Other countries and a number of non-governmental organizations favour a broader scope, including provisions on the domestic handling and use of transgenic organisms, as well as provisions on liability and compensation resulting from malpractice.

IV. EMERGING PRIORITIES

27. Conclusion of the negotiations on a biosafety protocol under the Convention on Biological Diversity will be an important step forward. In following up its implementation at the national level, the establishment of a participatory mechanism facilitating effective and constructive interaction between the private and public institutions (industry associations, United Nations and other international bodies, non-governmental organizations etc.) aimed at considering controversial issues and resolving conflicts of interest will be useful. Such mechanism may have a profound effect in assuring public confidence and providing useful inputs, inter alia, to the Commission on Sustainable Development, the Conference of the Parties to the Convention on Biological Diversity and other international forums. In establishing such a mechanism, the experiences gained by the ad hoc working group on biosafety of UNIDO/UNEP/WHO/FAO may be useful.

28. Institutional capacity-building and networking should be promoted by national Governments to ensure the promulgation and implementation of national policies for access to genetic resources, biosafety and intellectual property protection, along with the requisite capacity for implementation.

29. Developing countries should set up mechanisms to facilitate the evaluation of research and development activities in biotechnologies and the commercialization of those technologies, as well as to assess their ecological, health and socio-economic and ethical implications in specific contexts.

Notes

[1] Report of the United Nations Conference on Environment and Development, vol. I, Resolutions Adopted by the Conference (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex II.